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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/046,681	01/10/2002	Guoqing Chen	A-733A	1839

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U.S. Patent Operations/JWB
Dept. 4300, M/S 27-4-A
AMGEN INC.
One Amgen Center Drive
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EXAMINER	
FORD, JOHN M	

ART UNIT	PAPER NUMBER
1624	6

DATE MAILED: 11/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/046681	Chen et al
	Examiner	Group Art Unit
	J. M Ford	1634

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE THREE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☒ Claim(s) 1--62 is/are pending in the application.

Of the above claim(s) 37 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1--36 and 38--62 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____.

Attachment(s)

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Reference(s) Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☒ Other Exhibit A

Office Action Summary

The claims in the application are claims 1—62.

Claim 1 is rejected under 35 U.S.C. 112, 2nd paragraph and 1st paragraph. What is being claimed, and where is it supported?

On page 1 of claim 1 one finds the ring A is selected from a), b), c), d), The heterocyclic and heteroaryl expressions do not tell the reader what the hetero atoms are, how many, and where they are in the ring. Each variation is a different ring.

Heterocyclic and heteroaryl mean different things to different people. The USPTO only recognizes O, S, Se, Te, N, and C as atoms of a heterocyclic ring.

Page 2 of claim 1 continues with these open heterocyclic and heteroaryl: [illegible] term in R and R1. Same, R2 and R3, page 3 of claim 1.

what is the purpose of the proviso(s) in the last few lines of claim 1? See New Rule 105.

The heterocyclic rings possible is wide open to staggering possibilities.

Applicants place too much conception with the reader. The heterocyclic expression leaves open, which ones: Azines, Diazine, Triazines, Tetrazines. [illegible] Where are the starting materials in the specification? [illegible]

Conception of what the intended heterocyclic ring, may be, should not be left to the reader.

[illegible] the specification does not [illegible]

One needs to know exactly where, in the ring, the hetero atoms are: 1, 2 or 1, 3 or 1, 4 or 1, 2, 4 or 1, 3, 4, etc., (7 membered rings) as each is a different entity, with a separate search.'

One must clearly know what is being claimed.

One, on reading the indication of heterocyclic applied by applicant, has no idea where the heteroatoms are in the unknown ring.

Not all heterocyclic rings have been shown to be producible, as stable, at room temperature. What is the source of the starting materials? Where is the adequate representative exemplification in the specification to support the claim language?

The heterocyclic term presents a problem of lack of clear claiming, and support in the specification for the variables sought.

This rests specific conception with the reader.

What exactly is intended, and where is that supported in the specification?

A Markush listing of intended, conceived of, producible heterocyclic rings is what is needed here? It is not possible to classify and search the molecule, unless one knows exactly which heterocyclic ring is being claimed.

Applicants need to clam what they have demonstrated as a specific fact.

The heterocyclic expressions in claims 1 and 2 are not acceptable, as they do not indicate, exactly, clearly, and specifically, what heterocyclic ring is being claimed. These expressions rest specific conception with the reader, and the specification does not include the source of the starting materials for the rings.

which applicant now claims. One must be able to tell from a simple reading of the claim, what it does and not encompass.

Why? Because that compound claim precludes others from making, using, or selling that compound for 17/20 years. Therefore, one must know what compound is being claimed.

Assuming that applicant is claiming what he regards as his invention, there are in reality only two basic reasons for rejecting claims under 35 U.S.C. 112; first is that language used is not precise enough to provide a clear-cut indication of the scope of the subject matter embraced by claim; this grounds finds its basis in the second paragraph of section 112; second is that language is so broad that it causes the claim to have a potential scope of protection beyond that which is justified by specification disclosure; this ground stems from the first paragraph of section 112; merits of language in claim must be tested in light of these two requirements.

The heterocyclic and heteroaryl variable is not precise and definite enough to provide a clear-cut indication of the scope of the subject matter embraced by the claim. The heterocyclic concept is so broad that it causes the claim to have a potential scope of protection beyond that which is justified by the specification disclosure.

The written description is considered inadequate here in the specification. Conception should not be the role the reader. Applicants should, in return for a 17/20-year monopoly, be disclosing to the public that which they know as an

actual demonstrated fact. The disclosure should not be merely an invitation to experiment. This is a 35 U.S.C. 112, first and second paragraph rejection. If you (the Public) find that it works, I claim it, is not a proper basis for patentability; IN re Kirk, 153 U.S.P.Q. 48 page: 53.

The specification serves various purposes, it sets forth the prior art, that which applicants decided not to claim, or compounds that stop the infection, but kill the patient. The reader cannot tell the extent of the new invention, unless it is clearly set forth in the claims, out of the mixed pieces of information of the specification. The claims have to clearly set out that which is claimed.

The claims measure the invention, United Carbon Co. vs. Binney and Smith Co; 55 U.S.P.Q. 381 at 384, col. 1, end of first paragraph, Supreme Court of the United States (1942).

The U.S. Court of Claims held to this standard in Lockhead Aircraft Corp. vs. United States, 193 U.S.P.Q. 449, "claims measure the invention and resolution of invention must be based on what is claimed".

The CCPA in 1978 held "that invention is the subject matter defined by the claims submitted by the applicant. "We have consistently held that no applicant should have limitations of the specification read into a claim where no express statement of the limitations is include in the claim": In re Priest, 199 U.S.P.Q. 11, at 15.

The claim cannot be completely searched here, until we know what applicant feels heterocyclic and heteroaryl means.

The USPTO only recognizes: C, N, O, S, Se, or Te as atoms of a heterocyclic ring. Therefore, there is a need for applicants to indicate what they mean by heterocyclic.

Heterocyclic is not just a substituent; it is a whole body of art. Researchers often spend their entire life on hetero N heterocyclic compounds without ever getting to hetero O or hetero S compounds. Many heterocyclic compounds, within the claim, have never been made.

Accordingly, claim 1 is rejected under 35 U.S.C. 112, 1st and 2nd paragraphs. What is being claimed? Where is the adequate representative exemplification in the specification?

The heterocyclic and heteroaryl term is not acceptable, as it reads on heterocyclic rings that require specific conception by the reader. Specific, producible, heterocyclic rings are not set forth in the claims. The source of the starting materials for the combinations claimed is not set forth.

Exactly what ring is being claimed, must be set forth in the claim.

Conception of what the intended heterocyclic ring, may be, should not be left to the reader.

Where is, what is intended by applicant, supported in the specification with sufficient representative exemplification? Note United Carbon Co. vs. Binney Smith Co. 55 U.S.P.Q. 381, Supreme Court of the United States (1942): "an invention must be capable of accurate definition, and it must be accurately defined to be patentable," above at 386.

Claims 2 and 3 are rejected for the reasons claim 1 was/is rejected. See the rejected terms on page 400 of the spec. in claim 3.

Likewise, claim 4 is rejected for the reasons claim 2 was rejected.

Claim 5 is an improvement because is begins to name A. However, A is a fused ring. We have no idea where the fusion of the named hetero ring is to begin. What side of pyridine, for instance is supposed to be between A1 and A2?

Further down on page 401, vague, rejected, heteroaryl terms reappear. Also, the rejected terms appear on page 402. Therefore, claim 5 is rejected under 35 U.S.C. 112, 2nd and 1st paragraphs.

Claim 6 is an improvement in A, but are too many rings to search in one application. See Rule 141: one invention per application.

Page 404 goes back to the rejected terms of claim 1.

Claims 7—13 are rejected as above noted in claim 6.

Claims 14 and 15 are rejected as being dependent on a rejected claim.

37 CFR 1.141 (a) calls for a reasonable number of species of the same invention. Claim 16 is not a reasonable number of species, nor are they of the same invention. Claim 16 should be limited to a reasonable number of species. Note the quinoline species.

Claim 17 is rejected for the reasons claim 1 was.

Claim 18 is rejected solely as it is dependent on a rejected claim; not for reasons peculiar to itself.

Claims 17 and 19 suggest a way to Group the application into individual applications each with that/those Genus, under 37 CFR 1.142.

Claim 19 is rejected for the reasons claim 1 was rejected.

Claims 20 and 24 and 26 are rejected solely as it is dependent on a rejected.

Claims 21, 22, 23 and 25 are rejected for the reasons claim 1 was rejected.

Claims 27, 29, 31, 33 are rejected for the reasons claim 1 was.

Claims 28, 30, 32, and 34 are rejected solely because of dependency.

Claim 35 should read: A pharmaceutical composition comprising an effective amount of a compound from any one of claims 1—34 and an inert carrier.

Treating cancer, broadly, cannot be allowed as set forth in claim 36.

Issenstead v. Watson, (DCDC 1957) 157 F Supp. 7, 115 USPQ 408 and Schindler v. Comr. Of Pats. (DCDC 1967) 269 F. Supp 630, 155 USPQ 838. Noted where an application discloses therapeutic effect on humans or a cure for a human disease as the utility of a claimed process, the District Court held that proof of such utility is required unless one of ordinary skill in the art would accept the utility statement as obviously valid and correct. Radoev. v. Brenner, Ferguson, (POBA 1957) 117 USPQ 229.

The Board of Appeals and the CCPA have held that even though the specification does not mention human use specifically, the Patent Office is not

precluded from finding an inference of human use and require proof thereof, when such use is a medical nature for the treatment of a serious disease, such as cancer. Ex parte Moore et al., (POBA 1960) 128 USPQ 8; In re Citron, (CCPA 1964 325 F2d 248, 139 USPQ 516; In re Hartop et al., (CCPA 1962) 311 F2d 249, 135 USPQ 419.

The Supreme Court declined to express a view as to whether patentability can be based on a product shown to inhibit the growth of tumors in laboratory animals. Brenner, Comr. Pats. v. Mason, (USSC 1966) 383 U.S. 519, 148 USPQ 689. The Court did state, however, that Congress did not intend that a patent be granted on a chemical did not intend that a patent be granted on a chemical compound, or a process for its production, whose sole "utility" consists of its potential role as an object of use-testing, reasoning the patent system is related to the world of commerce rather than the realm of philosophy ibid., 148 USPQ at 696.

The utility of a process for producing remissions in patients suffering from chronic myeloid leukemia was established by clinical reports and data, the acceptance of the drug employed by the Food and Drug Administration and by the American Medical Association Council on Pharmacy, the Board noting that remission, not cures, were alleged in the specification. Ex parte Timmis, (POBA 1959) 123 USPQ 581. Evidence involving a single compound and two type of cancer, was held insufficient to establish the utility of claims directed to a method

of treating seven type of cancer with member of a class of several compounds. In re Buting, (CCPA 1969) 418 F2d 540, 163 USZPQ 689.

Claim 36 is also rejected under 35 U.S.C. 112 1st and 2nd paragraph for the reasons claim 1 was rejected.

Claim 37 is a different invention apart. The agreement to examiner one use of the elected compound (MPEP 806.05 (h) with the elected compounds is based on the method claim being of the same scope as the compound claim genus (eventually arrive at as the compounds to be examined here), that is a particular value of A.

Claim 37 has additional active ingredients that make it of a different scope.

Claim 38 is directed to the broadly stated: "angiogenesis". Applicants need to elect which utility is to be examined here. MPEP 806.05(h) provides for restriction where it is shown that the compounds may be used for more than one purpose. The claims become evidence claims to that allegation see claims 36, 38, 40.

Claims 38 and 40 are rejected for the reasons claim 1 was rejected.

Claim 39 violates 35 U.S.C. 101 and 35 U.S.C. 112, since it is drafted in terms of use. See Clinical Products vs. Brenner, 255 F. Supp. 151; 149 USPQ 475 (D.C. District Columbia 1966).

Claim 39 is rejected as human therapy is too vague.

A disclosure that the claimed compounds can be used for "technical and pharmaceutical purposes" does not meet the requirements of 35 USC 112. In re Diedrich (CCPA 1963) 318 F2d 946, 138 USPQ 128.

KDR – related disorders in claim 40 is not a real world utility.

The recent utility guidelines set by PTO require applicants to meet the requirements as stated in Brenner v. Manson in, 148 US PQ 689, Which requires that utility be developed to a point where "specific benefits in currently available form". Similar is the "immediate benefit to the public" standard that Nelson v. Bowler, 206 USPQ 880 refers to. The standard set forth in the concurring opinion of In re Hartop, 135 USPQ 419 is "whether the invention has been brought to such perfection as to be capable of practical employment". This language is echoed in Bindra vs. Kelly, 206 USPQ 570.

Assays or Laboratory Tests are not acceptable uses.

A broad disclosure of utility as in the cited claims cannot be deemed in compliance with 35 U.S.C. 101 and 35 U.S.C. 112, first paragraph. A real world utility required. The PTO has amended the guidelines to clarity "specific utility".

The court focused on the fact that the applicants failed to identify a "specific utility" in Brenner v. Manson.

This requirement of one specific utility, is consistent with Unity of Invention Practice in International Applications and National Phase Applications in Rule 475 under 35 U.S.C. 371, and PCT Rule 13.2 for PCT applications.

Claim 41 is rejected for the reasons claim 40 was. All proliferative disorders is not one specific utility.

Claim 42 is rejected as inflammation related disorders is too vague. Why is claim 42 dependent on claim 12? Claim 12 is not a method.

Claims 43, 45, 47, 49, 51, and 53 are rejected for the reasons claim 1 was/is.

Claims 44, 46, 48, 50, 52, and 54 are rejected as it is dependent on a rejected claim. What is Boc? Page 457.

Claim 55 is a list of ultimate species in one claim, as if to avoid fees. The form is not acceptable.

There is a different claim requirement in 37 CFR 1.141(a) for each ultimate species, as claim 55, here, avoids fees. The word "different" was added to stop abuse of the Rule 141.

In 1964 when I started, here, as an Examiner there was a 5 species requirement. That was changed to a reasonable number. Then the word "different" was inserted to specify that each species had to be a different claim, so the US"PTO would not lose so much money on the claim.

Claim 55 is an aggravated, multiple page, example of listing ultimate species in one claim to avoid fees. 37 CFR 1.141 (a) is said by In re Fressola to have the force of law, 22 USPQ 2nd 1828.

Claim 55 is rejected as failing to comply with 37 CFR 1.141(a). Claim 55 is more than a reasonable number of species. Claim 55 is a list of ultimate

species. Applicants paid $18.00 for claim 55, It costs $45.00 to search each species on CAS-on-line. Each species of claim 55 has to be searched separately. The USPTO is losing money on claim 55. There is no generic concept. Each species has to be separately written out, and input, into the CAS-ON-LINE search system separately.

Claim 55 is rejected, as it is an aggravated example of abuse of the Rules. Claim 55 is not a reasonable number of species.

In re Fressola, 22 USPQ 2nd 1828, indicates that the Examiner may reject for applicant's failure to follow a Rule, see the last Office Action. Claim 55 in an Aggravated example of ultimate species listed in a claim, as it to avoid fees. Claim 55 is not a Markush claim. Claim 55 is a list of ultimate species. 37 CFR 1.141 (a) provides for a reasonable number of species to be examined with the genus. Claim 55 is an aggravated example of ultimate species, each of which has to be drawn out, and classified, and searched. I cannot tell if it is patentable or not. Time is simply not provided for that type search, to permit that determination. Claim 55 is not searchable in the time provided.

Claim 55 is not a Markush claim, and is a list of ultimate species. See the directive of Richard A Wahl, August 10, 1968, and provided as Exhibit A.

Claims 56 and 59 are rejected as being dependent on a rejected claim. We do not know from claim 56 how A is bonded in. Which side is fused?

Claims 57 and 58 and 60 and 62 are rejected for the reasons claim 1 was rejected.

Claims 61 and 62 are rejected as being dependent on a rejected claim.

The 1449 forms are noted.

We need to arrive at a specific A, before the 1449 info. can be related to the claims; 37 CFR 1.141: one invention per application.

Completeness of examiner's action.

The examiner's action will be complete as to all matters, except that in appropriate circumstances, such as misjoinder of invention, fundamental defects in the application, and the like, the action of the examiner may be limited to such matters before further action is made. However, matters of form need not be raised by the examiner until a claim is found allowable.

JOHN M. FORD
PRIMARY EXAMINER
Group Art Unit 1624

John M. Ford:jmr

November 18, 2003

Exhibit A Seal to Complaint

U.S. DEPARTMENT OF COMMERCE
OFFICIAL GAZETTE of the UNITED STATES PATENT OFFICE
September 10, 1968 Volume 854 Number 2

PATENTS

NOTICES

Dependent Claims

The Notice on dependent claims of June 8, 1966 (828 O.G. 1) is modified as follows:

With particular reference to the second full paragraph, claims dependent on a genus which purport to be dependent but are in fact ultimate species do not qualify as true dependent claims. Exemplary of such claim forms are those which depend on a formula but which recite all variables in such manner that no further specificity is possible as well as those claims which name a specific compound and add, "according to claim 1" which is superfluous as far as the claim content is concerned. In summary, claims to ultimate species are not considered dependent claims. Although accepted for filing, claims of this type will be objected to and not acted on unless made independent by amendment and supported by the appropriate fee.

RICHARD A. WAHL,
Assistant Commissioner.

Aug. 19, 1968.